#16/86
4-9-03

Attorney Docket No. BERL-020/04US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of Dan W. URRY

Serial No.:	09/841,321	Examiner:	PHAN, Hieu
Confirmation:	6851	Art Unit:	3738
Filed:	April 23, 2001		

For: **INJECTABLE IMPLANTS FOR TISSUE AUGMENTATION AND RESTORATION**

Commissioner for Patents
Washington, D.C. 20231

RESPONSE TO RESTRICTION REQUIREMENT AND ELECTION OF SPECIES REQUIREMENT

Details of Official Action

1. In part 1 on page 2 of the Official Action mailed October 2, 2002, Examiner Phan indicated that the present application contains claims directed to the following patentably distinct species of the "claimed second peptide unit":

A) Specie 1: SEQ ID NO: 46

B) Specie 2: SEQ ID NO: 47

C) Specie 3: SEQ ID NO: 52

2. Examiner Phan then indicated in part 2 on page 2 that the application contains claims directed to the following patentably distinct species of the "claimed polymer":

D) Specie 1: Polymer is a nonapeptide

E) Specie 2: Polymer is a pentapeptide

F) Specie 3: Polymer is a tetrapeptide

Examiner Phan then indicated that upon election of one of the specie above (i.e., election of a "nonapeptide, pentapeptide, or tetrapeptide" polymer), another election is required:

G) Sub-Specie 1: Pentapeptide

I: SEQ ID NO: 17

II: SEQ ID NO: 20

III: SEQ ID NO: 43

IV: SEQ ID NO: 44

V: SEQ ID NO: 45

VI: SEQ ID NO: 48

VII: SEQ ID NO: 49

VIII: SEQ ID NO: 51

H) Sub-Specie 2: Tetrapeptide

I: SEQ ID NO: 16

II: SEQ ID NO: 41

III: SEQ ID NO: 42

IV: SEQ ID NO: 50

3. Examiner Phan then indicated that applicant is required "to elect a single disclosed species for prosecution on the merits" under 35 U.S.C. 121 and stated that "no claims are generic." Standard language was also included in the Official Action indicating that applicant must "include an identification of the species that is elected consonant with this requirement" and provide "a listing of all claims readable" on the elected species.

Response to Official Action

Applicant first notes that the Official Action does not specifically identify whether various parts of the Official Action are being presented as a restriction requirement or an election of species requirement. Reference to made to sections of the code and regulations relating to restriction requirements (35 U.S.C. 121 and 37 CFR 1.141), but the wording used in certain sections of the Official Action is set out in a

manner similar to the wording of 37 CFR 1.146, which is directed to election of species requirements.

Based on a telephone called made by the undersigned to the Examiner to clarify these points, applicant understands that a restriction requirement has been made requiring election of a pentapeptide, tetrapeptide, or nonapeptide polymer and that other aspects of the Official Action are related to an election of species requirement requesting identification of a species for initial examination. Accordingly, this response is set out in that manner. If Examiner Phan intended differently, he should re-issue the Official Action with appropriate clarification.

Additionally, applicant notes for the record that there is in fact no "claimed polymer." The *invention* instead is directed to a "*method for tissue augmentation or restoration* in a mammal ... comprising ... injecting a polymer [having certain characteristics] at a tissue site" (claim 1) Applicant assumes that the election/restriction requirements set out in the Official Action, which are worded as if directed to polymer species, are based in fact on an understanding that *use* of a polymer type named in the Official Action is being restricted from use of a different polymer type. Clarification is requested, if this is not the Examiner's intention.

Finally, application notes for the record claim 1 is clearly a generic claim, as it mentions "nonapeptide, pentapeptide, and tetrapeptide monomeric units," which are all three of the groups set out by the Examiner in section 2 on page 2 of the Official Action (the restriction requirement). Use of *any* specific monomeric unit, such as the specific pentapeptide unit set out in the individual species identified below, would fall within the scope of this claims, as would use of a copolymer that contains any individual "second peptide unit" (copolymers are included within the scope of claim one, as are mixtures of polymers). Thus, there is a generic claim already pending that covers all "species" identified by the Examiner, in contrast to the Examiner's statement at the end of numbered paragraph 3 on page 3 of the Official Action that "[c]urrently, no claims are generic." Accordingly, since there is a generic claim now pending that covers all possible species, applicant assumes that the provisions of 37 CFR 1.141 will apply to the following election.

Elections

In response to the restriction requirement directed to the different types of monomer units in a polymer used in the method of the invention (paragraph 2 on page 2 of the Official Action), Applicant elects group E (species 2), namely "pentapeptides." It is noted for the record that "pentapeptides" are not the polymers being used but are monomers of a polymer recited in the claims, which in this case can be pure polypentapeptides or copolymers of pentapeptide monomers and other monomers. (The pentapeptide monomers are themselves formed from smaller monomers, namely individual amino acids.) Thus, the election of "pentapeptides" includes use of polypentapeptides, copolymers containing pentapeptides, and mixtures containing either type of polymer.

In response to the requirement for an election of species under 37 CFR 1.146 *for identification of a polymer* (the plain language of the election requirement), applicant elects the single disclosed species set out in the specification as Seq. ID No. 13:

$[(GVGVP)_{10}\text{-}GVGVPGRGDSP\text{-}(GVGVP)_{10}]_n$ Seq. ID No. 13

This sequence can be written in the following equivalent manner, which better shows its relationship to the substructures set out by Examiner Phan:

$[(GVGVP)_{11}\text{-}GRGDSP\text{-}(GVGVP)_{10}]_n$

This structure identifies and thus complies with all of the other election requirements set out in the Official Action. That is to say, the elected species contains two substructures GVGVP and GRGDSP, which are a basic pentapeptide building block and a "second peptide unit," respectively. The second peptide unit GRGDSP is Seq. ID No. 46 (species 1 in paragraph 1 on page 2 of the Official Action), while the pentapeptide GVGVP is Seq. ID No. 20 (sub-species II under part 2.G on page 2 of the Official Action).

To the extent that the election requirement was directed to use of polymers of the three general types set out in claim 1 (i.e., those containing pentapeptide, tetrapeptide, or nonapeptide monomers), no traversal is made, as 37 CFR1.141 should allow these species to be examined and granted together (there being only three species).

However, if applicant has misunderstood the Examiner and if the Official Action was intended to restrict species covered by claim 1 from each to some greater extent than the three general types mentioned (which is one possible reading of the language used in the Official Action), such a requirement is traversed, and clarification and/or reconsideration of what was intended is requested. There has been no statement identifying what dividing lines between "species" would be in such a case (e.g., how would copolymers that contain two of the specific pentapeptide monomers be treated?). Such restriction would be improper without clarification, as applicant has no opportunity to fully respond (37 CFR 1.143) to an unstated restriction requirement based on undefined compositions.

Furthermore, since all of the polymer compositions can be made by chemical polymerization (in the normal manner of making polymers) and are not biologically active (unless designed to be so by selection of a specific "second sequence" inserted into the basic structure), they are simply polymers that happen to made from amino acids. A common search of the use of the entire group of named polymers should be reasonably available to the Examiner. See the many earlier patents to the current inventors (search under the name Urry, or see the list of patents listed in the specification) where composition and use patents involving polymers made from pentapeptide, tetrapeptide, and nonapeptide monomers have been examined and granted as a unit.

Identification of claims reading on elected species

Before a list is given of claims reading on "a single disclosed species," it must be noted that the claims can read – or not read – on a particular composition containing any specific polymer sequence, such as one having the chemical structure of Seq. ID No. 13, *depending on conditions not specified by the chemical structure itself.* After all, the claims are not directed to a polymer *per se* but to a method that uses a polymer that is

based on pentapeptide, tetrapeptide, or nonapeptide monomers and that has certain specified physical properties. Thus, a composition used in a given injection could comprise mixtures of polymers including the one identified by Seq. ID No. 13 and in addition containing other polymers having other sequences that meet the remaining characteristics of a given claim. It could also contain other substances mixed therewith that would, e.g., modify the viscosity of the composition (relevant to claim 2) or cause the polymeric mass as a whole to be crosslinked (claim 3) or not.

Accordingly, *all* of the currently pending claims, claims 1-34, read on the "elected species" if the elected species is considered to be a *polymer* (which is the "species" defined by the wording used in the Official Action) as opposed to a species of the actually claimed *method*. In the polymer case, since the compositions being injected can contain mixtures of individual polymers that include the one identified by Seq. ID No. 13, if the other polymers present in the mixture have characteristics such that the limitation of the claims are met, all claims read on such an elected "species."

On the other hand, if one assumes that the *only* polymer present in a composition being injected is the polymer identified by Seq. ID No. 13 and that the polymer has been crosslinked after formation, e.g., by radiation as described in the specification, the following claims would read on use of such a composition (assuming, as noted, that other limitations of the claim not related to the polymer are met): Claims 1-5, 7, 9, 11, 14-23, 25, 27, 29, and 31-34. For the sake of moving prosecution forward, applicant identifies use of such a polymer in the method set out in claim 1 as the "single disclosed species" of the invention, should the Examiner, after reading this response, believe that the "single disclosed species" of the invention should more closely specify an injectable composition, rather than simply a monomeric unit used in forming a polymer used in the composition.

Conclusion

A Request for an Extension of Time to file this response in included in the concurrently filed papers

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned at (650) 843-5070.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, or 1.21 that may be required by this paper, to the extent not already covered by the enclosed extension of time, and to credit any overpayment, to Deposit Account No. 03-3117.

Dated: March 20, 2003

Respectfully submitted,
COOLEY GODWARD LLP

By: _____
Richard L. Neeley
Reg. No. 30,092

Cooley Godward LLP
ATTN: Patent Group
Five Palo Alto Square
3000 El Camino Real
Palo Alto, CA 94306-2155
Tel: (650) 843-5000
Fax: (650) 857-0663

RLN/ct

634440 v1/PA